UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

Jill A. Whitcomb,

Plaintiff,

Case No. 13-C-990

v.

Sylvia Matthews Burwell,
Secretary of Health and Human Services,

Defendant.

DEFENDANT'S RESPONSE TO PLAINTIFF'S REQUEST FOR JUDICIAL REVIEW

I. Introduction

The present litigation involves Plaintiff's challenge of the Secretary's final decision denying coverage for a Medtronic MiniMed Paradigm Real Time System and Continuous Glucose Monitoring System ("CGM"). The CGM is a device that continually reads a person's blood glucose level. It involves embedding a sensor subcutaneously into a person's body, then having a transmitter send blood glucose readings to a receiver/insulin pump which is worn by the person. The long-term use of CGMs is not covered by Plaintiff's Medicare Advantage plan or original Medicare. Indeed, the CGM for which Plaintiff seeks coverage is excluded from Medicare coverage by Policy Article A47238. Despite this, Plaintiff urges this Court to reverse the Secretary's final decision and order coverage for the excluded CGM. Plaintiff's request for coverage essentially asks this Court to disregard Medicare policy and find that the Secretary's final decision is contrary to law. In contrast, the Secretary respectfully requests that the Court

affirm her final decision because it is consistent with Medicare coverage rules and the benefits provided for under Plaintiff's Medicare Advantage plan.

II. Statutory and Regulatory Framework

A. Overview of the Medicare Advantage Program

The Medicare program, Title XVIII, 42 U.S.C. § 1395 *et seq*., is a federally funded and administered health insurance program for eligible persons who are (1) 65 years of age or older who are entitled to social security retirement benefits, or (2) disabled or have end stage renal disease and are entitled to social security disability benefits. 42 U.S.C. § 1395c. The Secretary administers the Medicare program through the Centers for Medicare & Medicaid Services ("CMS"), a component agency of the United States Department of Health and Human Services.

The Medicare program is divided into four major components. Part A, the hospital insurance benefits program, provides health insurance coverage for services including, but not limited to, inpatient hospital care, post-hospital care in a skilled nursing facility, and post-hospital home care services. 42 U.S.C. §§ 1395d - 1395i-5; 42 C.F.R. Part 409. Part B, the supplemental medical insurance benefits program, generally pays for a percentage of certain medical and other health services that are supplemental to the benefits provided by Part A, including, but not limited to, physician services, certain home health services, and outpatient physical and occupational therapy. 42 U.S.C. §§ 1395k and 1395l. Part C, also known as the Medicare Advantage ("MA") program, allows CMS to contract with public and private entities to provide, at a minimum, Medicare benefits to certain Medicare beneficiaries. 42 U.S.C. § 1395w-21 *et seq*. Part D provides prescription drug coverage to qualifying enrollees. 42 U.S.C. § 1395w-101 *et seq*.

The present case arises under Part C as it involves Plaintiff's request that UnitedHealthcare/SecureHorizons ("SecureHorizons"), a Medicare Advantage organization, provide coverage for a CGM.[1] The MA program, formerly known as Medicare + Choice, allows eligible Medicare beneficiaries to enroll in MA plans to receive their Medicare benefits. 42 U.S.C. § 1395w-21 *et seq.*; 42 C.F.R. Part 422. A MA plan refers to the "health benefits offered under a policy or contract by a MA organization that includes a set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan." 42 C.F.R. § 422.2. MA plans may be coordinated care plans, like health maintenance organizations, medical savings accounts, or private fee-for-service plans. 42 U.S.C. § 1395w-21(a)(2); 42 C.F.R. § 422.4. In this case, Plaintiff was enrolled in AARP MedicareComplete Plus, a MA coordinated care plan offered by SecureHorizons.

All MA plans must provide, at a minimum, basic benefits. Basic benefits include the benefits offered by original Medicare (meaning Medicare Parts A and B). 42 U.S.C. § 1395w-22(a)(1); 42 C.F.R. § 422.100(c)(1). With respect to basic benefits, MA organizations are required to comply with national coverage determinations ("NCDs"), general coverage guidelines included in the Medicare manuals and instructions, and written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered under the MA plan. 42 C.F.R. § 422.101(b). To encourage beneficiaries to enroll in MA plans, many MA organizations offer supplemental benefits, which are benefits that go beyond the benefits offered by original Medicare. 42 U.S.C. § 1395w-22(a)(3); 42 C.F.R. § 422.100(c)(2); 42 C.F.R. § 422.102.

[1] Plaintiff has characterized the present case as arising under Part B. However, because the case involves Plaintiff's request for coverage under her MA plan, the case arises under Part C, not Part B (although Part B coverage rules apply to the extent that the MA organization relied upon them in determining coverage).

A MA plan's benefits must be set forth in a standardized form, known as the Evidence of Coverage ("EOC"). 42 U.S.C. § 1395w-22(c)(1)(B); 42 C.F.R. § 422.111. CMS provides model EOCs that are used by MA organizations. The MA organizations only alter the model EOCs by adding information regarding their MA plans' specific benefits, cost sharing, and rules governing the receipt of benefits. MA organizations are required to provide EOCs to beneficiaries upon their enrollment and then at least annually thereafter. *Id.* Ultimately, the EOC serves as one of the documents that governs the relationship between an enrollee and the MA organization.

B. NCDs, LCDs, and Policy Articles

For items and services to be covered by Medicare, they must be eligible for coverage under a defined Medicare benefit category, be reasonable and necessary for the diagnosis or treatment of an injury or illness, and meet all applicable statutory and regulatory requirements. While many coverage determinations are made on a case-by-case basis, the Secretary may issue a national coverage decision (NCD) that sets forth a national policy with respect to coverage for a certain item. 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R. § 405.1062(a). NCDs are binding on Medicare's Administrative Contractors ("MACs") that process claims, qualified independent organizations, Administrative Law Judges ("ALJ"), and the Medicare Appeals Council ("the Council"). 42 C.F.R. § 405.1060(a)(4).

Unlike NCDs, Local Coverage Determinations ("LCD") are coverage determinations that are issued by MACs (formerly referred to as intermediaries and carriers) relating to coverage of items and services within the jurisdiction of a specific MAC. 42 U.S.C. § 1395ff(f)(2)(B). Until the passage of the Benefits Improvement and Protection Act of 2000 ("BIPA"), LCDs were known as Local Medical Review Policies ("LMRPs"). The primary difference between LMRPs

and LCDs is that LMRPs included payment and coding information. 42 C.F.R. § 400.202; *See also* Local Coverage Determination http://www.cms.gov/Medicare/Coverage/DeterminationProcess/LCDs.html. In contrast, LCDs typically only include the reasonable and necessary information needed for coverage. Payment and coding information is now included in Policy Articles that are specifically linked to the associated LCD. *Id.* Thus, a LCD and its associated Policy Articles together provide MACs with the information needed to determine whether an item or service is covered.

ALJs and the Council are not bound by LMRPs or LCDs. 42 C.F.R. § 405.1062. However, ALJs and the Council are required to give these policies substantial deference if they are applicable to a particular case. 42 C.F.R. § 405.1062(a). If the Council or an ALJ declines to follow a LMRP or LCD, the decision must explain why the policies were not followed. Any such decisions are not precedential. 42 C.F.R. § 405.1062(b).

MA organizations, though, are required to comply with: 1) NCDs; 2) general coverage guidelines included in original Medicare manuals and instructions; and 3) written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under a MA plan. 42 C.F.R. § 422.101(b). Thus, unlike the Council and ALJs, MA organizations do not have the authority to decline adhering to LMRPs and LCDs.

C. Overview of Coverage for Continuous Glucose Monitors under Original Medicare

The Medicare Program, 42 U.S.C. §§ 1395 to 1395ii, pays for covered medical care provided to eligible aged and disabled persons. To be "covered," the medical care must be "reasonable and necessary," 42 U.S.C. § 1395a(a)(1)(A), meet coverage guidelines, and not be excluded by any other provision. Coverage for blood glucose monitors is discussed in NCD for Home Blood Glucose Monitors ("NCD 40.2"), A.R. 588-590, Local Coverage Determination

("LCD") for Glucose Monitors ("LCD L27231"), A.R. 579-587, and Local Coverage Article for Glucose Monitors – Policy Article – October 2008 ("Policy Article A47238"), A.R. 591-594.

NCD 40.2 discusses a limited type of blood glucose monitor that may be covered by Medicare. CGMs are not discussed. Specifically, NCD 40.2 states, in part:

> Blood glucose monitors are meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary with the device used, inserts it into the device to obtain a reading. Lancets, reagent strips, and other supplies necessary for the proper functioning of the device are also covered for patients whom the device is indicated. Home blood glucose monitors enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment. Studies indicate that the patient's ability to carefully follow proper procedures is critical to obtaining satisfactory results with these devices. In addition, the cost of the devices, with their supplies, limits economical use to patients who must make frequent checks of their blood glucose levels.

A.R. 589.

Like NCD 40.2, LCD L27231 focuses on metered blood glucose monitors that require a beneficiary to place a blood sample on a reagent strip before placing it into the monitoring device to be read. A.R. 580. Additionally, LCD L27231 explains that Medicare will cover an extensive amount of supplies, such as lancets and reagent strips, provided a beneficiary's physician documents the need. A.R. 581.

Prior to July 1, 2005, the information in LCD L27231 was included in a LMRP. A.R. 28, 585. After July 1, 2005, the LMRP was converted to LCD L27231 and associated Policy Article A47238. *Id.* Policy Article A47238 further outlined Medicare's coverage of glucose monitors for beneficiaries living in Wisconsin. A.R. 591-594. The portion of Policy Article A47238 that

is relevant to the present case states, "continuous glucose monitors (A9276-A9278) are considered precautionary and therefore non-covered under the DME benefit." A.R. 592.

III. Statement of Facts

A. Relevant Medical Facts Relating to Plaintiff's Request for a CGM

Plaintiff is diagnosed with Type I diabetes. A.R. 429. The primary condition that caused her to request a CGM is hypoglycemia unawareness. *Id.* According to Plaintiff's treating nurse practitioner, Plaintiff's caregiver had to provoke Plaintiff into checking her blood glucose levels several times per week. *Id.* Consequently, Plaintiff's caregiver requested the help of a CGM so that he could monitor Plaintiff's blood sugar before she experienced a hypoglycemic event. *Id.* Plaintiff's treating nurse practitioner agreed that Plaintiff could benefit from a CGM because it shows real time glucose values that would allow Plaintiff and her caregiver to respond quickly to an imminent hypoglycemic event, which could have significant consequences. *Id.* According to Plaintiff's nurse practitioner, Plaintiff successfully used a CGM, meaning that during a one month period, Plaintiff experienced six hypoglycemic events rather than 22. *Id.* However, Plaintiff noted that there were times when the CGM readings were not as accurate as when she obtained her values using a metered blood glucose test. A.R. 467. Even so, Plaintiff requested that SecureHorizons authorize coverage for a CGM.

B. SecureHorizons Evidence of Coverage and Coverage of CGMs

Diabetic supplies are covered by SecureHorizons as outlined in its internal coverage policies and its members' EOCs. As discussed above, enrollees in a MA plan, such as Plaintiff, receive an EOC that sets forth the covered benefits under a MA plan. Here, Plaintiff received SecureHorizons' EOC for her MA plan, AARP MedicareComplete Plus. A.R. 596-792. The EOC specifically advises enrollees that services, supplies, and equipment must be provided

according to the coverage guidelines established by Medicare and be medically necessary. A.R. 633. Indeed, the EOC highlights that it excludes services that are not reasonable and necessary according to the standards set forth by original Medicare. A.R. 667. Thus, consistent with original Medicare, SecureHorizons covers items such as blood glucose monitors, test strips, lancets, and glucose-control solutions used to check the accuracy of the testing strips. A.R. 647.

SecureHorizons' internal policy that explains the coverage described in the EOC is its Diabetic Management, Equipment and Supplies Policy. A.R. 570-578. Coverage for home glucose monitors mirrors the coverage requirements outlined in NCD 40.2 and LCD L27231. A.R. 571-572. Section 5 of the policy specifically discusses continuous glucose monitoring systems. A.R. 572. This portion of the policy acknowledges that Medicare does not have a NCD relating to the short-term use of CGMs and that only one contractor has a LCD for the short-term use of professional-grade CGMs (as opposed to personal CGMs like the one requested by Plaintiff). A.R. 572. Given the sparse coverage information relating to the short-term use of professional-grade CGMs, SecureHorizons decided that it would cover the short-term use of professional-grade CGMs for all of its enrollees. *Id.*

SecureHorizons' policy notes that CGMs are intended to supplement, not replace, standard self-monitoring of blood glucose checks performed with a fingerstick. A.R. 573, 577. The purpose of using a CGM is to obtain values over a short period of time so that the treating practitioner can adjust treatment regimens depending on the data and patterns that it might show. *Id.* Further, the policy recommends that values obtained via CGM be validated through the use of a metered blood glucose monitor. *Id.* Because the policy recognizes the limitations of using CGMs, it goes on to state, "*Long term use or frequent use of continuous glucose monitoring will be* ***denied as not medically necessary.***" *Id.* (emphasis in original). Further, the policy states that

because no LCDs for long-term use of CGMs exist, SecureHorizons will adhere to applicable Policy Articles, such as Policy Article A47238. Overall, SecureHorizons' coverage policy adheres to the coverage criteria set forth by Medicare. Accordingly, it does not cover the long-term use of a CGM like the Minimed Real-Time CGMS (the system Plaintiff requested).

C. Procedural Facts

On May 9, 2011, Plaintiff requested that SecureHorizons cover a CGM with the HCPCS code A9276. A.R. 302-303. SecureHorizons denied Plaintiff's request on May 13, 2011. A.R. 276-277. SecureHorizons advised Plaintiff that it denied coverage for the CGM because long-term continuous glucose monitoring systems are not covered by Medicare. A.R. 276. Additionally, SecureHorizons informed Plaintiff that the requested CGM was not a covered benefit under her MA plan. *Id.*

On May 13, 2011, Plaintiff appealed SecureHorizons' initial determination denying coverage for the CGM. A.R. 266. Although SecureHorizons denied Plaintiff's request for an expedited appeal, it advised Plaintiff that her appeal would be considered through the standard 30-day appeal process. A.R. 273-274. On June 10, 2011, SecureHorizons affirmed its decision denying coverage for the requested CGM. A.R. 266-267. In its redetermination decision, SecureHorizons stated:

> Non-continuous glucose monitors are a Medicare covered benefit per National Coverage Determination (NCD) for Home Blood Glucose Monitors (40.2). Per Local Coverage Article for Glucose Monitors – Policy Article – October 2008 (A47238); "Continuous glucose monitors (A9276-A9278) are considered precautionary and therefore non-covered under the DME benefit." The member's AARP MedicareComplete policy does not have a supplemental benefit for glucose monitoring that goes beyond the Medicare benefit. The denial is consistent with the benefit.

A.R. 266.

Pursuant to 42 C.F.R. § 422.592, SecureHorizons sent its decision to Maximus Federal Services ("Maximus"), the independent review entity, for review. A.R. 262-264. In its June 24, 2011 letter, Maximus advised Plaintiff that it agreed with SecureHorizons' decision that CGMs are not a covered benefit under the plan or original Medicare, as indicated in Policy Article A47238. A.R. 259-260. After Maximus issued its decision, Plaintiff wrote letters to Maximus challenging its decision. A.R. 210, 211. Consequently, Maximus re-issued its decision on June 8, 2012. A.R. 209. Subsequently, Plaintiff requested a hearing before an administrative law judge ("ALJ"). A.R. 195.

On February 6, 2013, the ALJ reversed SecureHorizons' decision denying coverage for the requested CGM. A.R. 79-89. The ALJ held that Plaintiff's request for a CGM should have been approved based on NCD 280.1, which contains the Durable Medical Equipment ("DME") Reference List, and NCD 40.2, which sets forth the criteria for coverage for home blood glucose monitors. A.R. 88. Specifically, the ALJ found that Plaintiff's condition satisfied the coverage criteria set forth in NCD 40.2 because Plaintiff was diagnosed with diabetes, her physician testified that she could be trained to use the CGM, and the CGM was designed for home use. *Id.* Additionally, the ALJ found that although he was not bound by LCD L27231, the Plaintiff satisfied the five criteria needed for coverage: 1) Plaintiff was diagnosed with diabetes; 2) Plaintiff's nurse practitioner ordered the CGM; 3) Plaintiff successfully completed training to use the CGM, as evidenced by her successful use of it; 4) Plaintiff would be able to use the CGM's results to assure appropriate glycemic control; and 5) the CGM is designed for home use. A.R. 52-53. While the ALJ acknowledged that Policy Article A47238 stated, "Continuous glucose monitors (A9276-9278) are considered precautionary and therefore non-covered under the DME benefit," he declined to adhere to the policy based on Plaintiff's medical condition. A.R. 51-53.

The ALJ also did not address the requirement that SecureHorizons adhere to local coverage determinations pursuant to 42 C.F.R. § 422.101(b).

SecureHorizons timely requested that the Medicare Appeals Council ("the Council") review the ALJ's decision. A.R. 36-41. SecureHorizons argued that its initial determination should have been affirmed because CGMs are not covered by original Medicare, and as a result, they are not covered by Plaintiff's MA plan. Additionally, SecureHorizons noted that it should not be required to cover the CGM because it was required to follow written coverage decisions of local carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered, like Policy Article A47238. A.R. 37.

The Council issued its decision reversing the ALJ on August 23, 2013. A.R. 21-29. The Council held that the ALJ mistakenly departed from the coverage standards outlined in LCD L27231 and Policy Article A47238. A.R. 27. In support of its conclusion, the Council found that neither NCD 40.2 nor LCD L27231 discuss CGMs. Rather, they refer to blood glucose monitors that are metered devices that determine blood glucose levels by testing a drop of blood that a beneficiary draws on a reagent strip. A.R. 27. Thus, according to the Council, the ALJ incorrectly applied the coverage standards contained within NCD 40.2 and LCD L27231. The Council stated, however, that it was significant that LCD L2723 incorporated the Policy Article that expressly excluded CGMs from coverage under Medicare. *Id.* Next, the Council clarified that although Medicare does not cover CGMs, it does not limit coverage for blood sugar testing supplies provided that a treating physician documents the need for additional supplies. A.R. 28. Finally, and in the Council's assessment most importantly, LCD L27231 indicates that the preceding LMRP was converted to LCD L27231 and the related Policy Article A47238 on July 1, 2005. *Id.* Thus, the Council held, the ALJ erred in declining to afford substantial deference to

the policies, as required by the regulations. *Id.* The Council noted that much of the testimony Plaintiff offered centered around her belief that Medicare needed to revisit its exclusion of CGMs from coverage based on recent research. However, as the Council correctly pointed out, challenges to the validity of the LCD and Policy Article must be processed through the appeals procedures set forth 42 C.F.R. Part 426. *Id.*

Plaintiff requested that the Council reconsider its decision. A.R. 11. In response, the Council explained that Plaintiff's belief that Medicare covered all DME that treated illnesses was incorrect. A.R. 6. Rather, the Council clarified that Medicare coverage for DME depends on whether the DME meets all of the coverage guidelines set forth in the Medicare statute, regulations, and policies. *Id.* In light of the fact that LCD L27231 and Policy Article A47238 together specifically exclude the CGM that Plaintiff requested, the Council found that its decision to reverse the ALJ was correct. Thus, the Council stated that its decision that SecureHorizons properly denied coverage for the requested CGM was the Secretary's final decision. A.R. 8.

The present litigation is Plaintiff's challenge to the Secretary's final decision.

IV. Standard of Review

Once the Secretary has issued her final decision regarding a Medicare claim, judicial review of that decision is available under 42 U.S.C. § 405(g); 42 U.S.C. § 1395w-22(g)(5) (setting forth the requirements for judicial review of claims involving Medicare beneficiaries enrolled in MA plans). Section 405(g) grants the Court "the power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing." Under this framework, the Court's task is limited to determining whether the Secretary's final decision is supported by

substantial evidence and is free from legal error. *Wood v. Thompson*, 246 F.3d 1026, 1029 (7th Cir. 2001). Substantial evidence means "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Richardson v. Perales*, 402 U.S. 389, 401 (1971). To determine if substantial evidence exists, the Court reviews the administrative record but does not re-weigh the evidence, resolve conflicts, decide issues of credibility, or substitute its judgment for the Secretary's. *Clifford v. Apfel*, 227 F.3d 863, 869 (7th Cir. 2000). If the Secretary's factual findings are supported by substantial evidence, they are conclusive. 42 U.S.C. § 405(g); *Wood*, 246 F.3d at 1029. However, this does not mean that the Court should simply rubber-stamp the Secretary's decision. *Clifford*, 227 F.3d at 869. Overall, absent legal error, the reviewing court must affirm a decision based on substantial evidence, even if the court would have decided the case differently. *Delgado v. Bowen*, 782 F.2d 79, 83 (7th Cir. 1986); *see also Wilkins v. Sullivan*, 889 F.2d 135, 140 (7th Cir. 1989) ("It is precisely this type of decision - made within the context of an extremely technical and complex field - that courts should leave in the hands of the expert administrators."); *Cutlip v. Sec'y of Health & Human Servs.*, 25 F.3d 284, 286 (6th Cir. 1994) ("If the Secretary's decision is supported by substantial evidence, it must be affirmed even if the reviewing court would have decided the matter differently, and even if substantial evidence also supports the opposite conclusion") (citations omitted).

V. Argument

A. The Secretary's Final Decision Affirming SecureHorizons' Denial of Coverage for Plaintiff's Requested CGM is free from Legal Error

In this case, the Secretary's final decision to deny coverage for the long-term use of a CGM is free from legal error. As the Council explained, the ALJ mistakenly applied NCD 40.2 and the coverage criteria contained therein to Plaintiff's request for a CGM. The plain language

of NCD 40.2 establishes that it applies to metered blood glucose monitors and not CGMs. NCD 40.2 states, "Blood glucose monitors are meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary with the device used, inserts it into the device to obtain a reading." A.R. 589. In contrast, a CGM is "a sensor system that is designed to continuously and automatically monitor interstitial glucose values in subcutaneous tissue." A.R. 577. In light of the fact that NCD 40.2 does not even remotely discuss coverage for CGMs, the Secretary acted within her discretion when she determined that NCD 40.2 is limited to coverage determinations relating to metered blood glucose monitors. Consequently, the Secretary correctly found that the ALJ mistakenly applied the coverage criteria in NCD 40.2 when evaluating whether coverage for a CGM was available under Medicare or Plaintiff's MA plan.

Similarly, the Secretary properly found that LCD L27231 did not provide coverage for the requested CGM. Like NCD 40.2, LCD L2731 provides coverage for blood glucose monitors that test a person's blood glucose levels through a blood sample that a person places on a reagent strip and which is then inserted into the testing device. A.R. 581. Thus, LCD L27231 provides coverage for lancets (A4259), blood glucose test reagent strips (A4253), glucose control solution (A4256), spring powered devices for lancets (A4258), and replacement lens shield cartridges for use with laser skin piercing devices (A4257) for those who meet the five criteria for coverage. *Id.* Again, the CGM for which Plaintiff sought coverage greatly differs from the blood glucose monitors described in LCD L27231. Indeed, the CGM for which Plaintiff seeks coverage does not use any of the items specifically referred to in LCD L27231. Instead, the components of the CGM include a sensor (A9276), a transmitter (A9277), and a receiver (A9278). A.R. 27. Thus,

the Secretary's decision that LCD L27231 does not provide coverage for Plaintiff's requested CGM was not arbitrary and capricious. Rather, the Secretary's decision was based on a sound reading and application of LCD L27231 and its associated Policy Article A47238.

As discussed above, when LMRPs were converted to LCDs, the LCDs focused on the reasonable and necessary coverage requirements and Policy Articles were introduced to provide information regarding payment and coding. Thus, as CMS has stated, "a local policy may consist of two separate, but closely related documents: the LCD and an associated article. The LCD only contains reasonable and necessary language. Any non-reasonable and necessary language a Medicare contractor wishes to communicate to providers may be done through the article. At the end of an LCD that has an associated article, there is a link to the related article and vice versa." *See* Welcome to the Medicare Coverage Database, http://www.cms.gov/medicare-coverage-database (last visited Nov. 24, 2014). Thus, when making a coverage determination, MA organizations and MACs look to LCDs and Policy Articles in the absence of a NCD.

Here, SecureHorizons' initial denial was based on the "Non-Medical Necessity and Payment Rules" set forth in Policy Article A47238. A.R. 56. Plaintiff argues that the Secretary mistakenly relied on Policy Article A47238 in making her final decision and that this Court should reverse the Secretary's final decision because the Policy Article is not entitled to any deference. Plaintiff's argument should fail. The Medicare Act does not include a list of items and services that are covered by Medicare. Instead, it "lists categories of items and services, and vests in the Secretary the authority to make determinations about which specific items and services within these categories can be covered under the Medicare program." 68 Fed. Reg. 55634, 55635. Coverage for an item or service is conditioned upon a determination "that a

service meets a benefit category, is not specifically excluded from coverage, and the item or service is reasonable and necessary." *Id.* Determining whether an item is reasonable and necessary is left to the discretion of the Secretary. *Heckler v.* Ringer, 466 U.S. 602, 617 (1984).

In this case, the Secretary determined that coverage for the requested CGM is not available under Medicare or Plaintiff's MA plan based on Policy Article A47238, which is linked to LCD L27231. While the Secretary agrees Policy Article A47238 does not carry the full force of law like a regulation, this does not mean that the Policy Article should not be afforded a substantial amount of deference. Policy Article A47238 specifically states that CGMs with HCPCs codes A9276-A9278 are considered precautionary and therefore not covered. A.R. 56. In relying on Policy Article A47238, the Secretary used her broad discretion and determined that the precautionary devices do not qualify for coverage. The fact that private insurers have covered CGMs for their private enrollees is irrelevant to whether CGMs qualify for coverage under Medicare. Similarly, that various organizations have opined regarding the efficacy of CGMs does not, in a coverage appeal, change the coverage status of CGMs. Rather, if Plaintiff wishes to challenge the NCD or LCD because they do not include CGMs, Plaintiff may do so using the process outlined in 42 C.F.R. Part 426. This case, though, is about the application of the coverage rules as they relate to Plaintiff's request. Thus, the Secretary's decision, which is based on her interpretation of the items and services that are covered by Medicare, should not be set aside because it is not contrary to law.

Notably, SecureHorizons, as a MA organization, was required to adhere to the LCD and the Policy Article when determining coverage. Pursuant to 42 C.F.R. § 422.101(b), MA organizations must comply with written coverage decisions issued by local MACs which have jurisdiction for claims in the geographic area covered by a MA plan. SecureHorizons' Diabetes

Management, Equipment and Supplies Policy, A.R. 570-578, complies with Policy Article A47238 and excludes coverage for the long-term use of a CGM like the one Plaintiff requested. While SecureHorizons could have offered the use of a long-term, personal CGM as a supplemental benefit, it has not done so. Instead, as stated in its EOC, SecureHorizons provides benefits consistent with the coverage rules established by original Medicare. A.R. 575. Accordingly, the EOC describes coverage for diabetic self-monitoring services as including the same items covered by NCD 40.2 and LCD L27231 (i.e. lancets, reagent strips, glucose control solutions, etc.). A.R. 647. In light of the fact that SecureHorizons did not offer the use of personal CGMs as a supplemental benefit, the Secretary correctly found that SecureHorizons' denial of the requested CGM was proper and consistent with the coverage rules established by original Medicare.[2]

Plaintiff attempts to show that the Secretary's final decision was arbitrary and capricious by submitting an ALJ decision that orders payment for a CGM for another beneficiary. Plaintiff's argument is unavailing. First, the regulations specifically state that ALJ decisions that do not adhere to a LCD have no precedential effect. 42 C.F.R. § 405.1062(b). Second, the decision Plaintiff focuses on involves a different MA organization that had previously covered CGMs for the beneficiary. Thus, the facts are readily distinguishable from the present case. Third, the parties to the present litigation are not privy to the other MA organization's decision regarding whether to appeal the ALJ's decision. Therefore, it is unclear whether the Council would have reversed the ALJ as it did in the present case. In light of the non-precedential effect of the submitted decision and the important differences between the cases, Plaintiff's attempt to

[2] SecureHorizons does offer coverage for the short-term use of a professional-grade CGM. According to SecureHorizons' policy, the short-term use of a CGM allows a treating practitioner to identify patterns and adjust treatment as necessary. Coverage, though, has not been extended to the long-term use of personal CGMs. SecureHorizons' coverage rules are consistent with Medicare's. A.R. 570-578.

cast the Secretary's final decision as inconsistent with previous decisions should fail. *See Wood*, 246 F.3d at 1034, citing *Friedrich v. Sec'y of Health & Human Servs.*, 894 F.2d 829, 835 (6th Cir. 1990) (single decision of the Medicare Appeals Council was "not significant" enough to support plaintiff's argument that the Secretary had not followed a consistent policy for denying coverage).

Despite the fact that the Secretary's final decision was correctly based on the applicable coverage rules for CGMs, Plaintiff urges the Court to disregard the coverage rules and order coverage for the CGM based solely on Plaintiff's medical condition. In other words, Plaintiff argues that the Secretary's final decision is not supported by substantial evidence. Plaintiff is correct that the Secretary's final decision can be reversed if it is not based on substantial evidence. *Wood*, 246 F.3d. at 1035. However, the Secretary does not dispute that Plaintiff suffers hypoglycemic unawareness and that this makes it difficult for her to monitor her blood glucose levels. As a result, Plaintiff's focus on whether the CGM is medically necessary is misplaced because the issue before this Court is whether the Secretary properly denied coverage for a CGM, despite the fact that the CGM may be medically necessary according to Plaintiff's nurse practitioner. *Id.* The reality is that Medicare does not cover all medically necessary services. *Wood*, 246 F.3d at 1035. Rather, to be eligible for coverage, items and services must be reasonable and necessary, meet coverage guidelines, and not be excluded. In other words, while Plaintiff may satisfy the requirement that items be medically necessary, this alone is insufficient to automatically result in coverage for a CGM. *See Goodman v. Sullivan*, 712 F.Supp. 334, 338 (S.D.N.Y. 1989) ("While Congress created specific exclusions from coverage and provided that in no case may payment be made for any expenses incurred for items and services which 'are not reasonable and necessary for the diagnosis or treatment of illness or

injury' it never provided that payment must be made at all times when services are deemed 'medically necessary.'").

The Secretary's final decision which affirmed SecureHorizons' denial of a CGM for Plaintiff is free from legal error. The decision was based on a sound analysis of the coverage rules governing diabetes self-monitoring items and services. Accordingly, the Secretary respectfully requests that the Court affirm her final decision.[3]

B. The Limitation on Liability Provision at 42 U.S.C. § 1395pp Does Not Apply

Plaintiff urges this Court to order the Secretary to pay for a CGM under 42 U.S.C. § 1395pp. This section, also referred to as the "limitation on liability provision," provides that if a Medicare beneficiary did not know (and could not reasonably have been expected to know) that a service was not covered, but the provider of services did know (or could have been expected to know) of the non-coverage, then Medicare will deny payment to the provider, but the beneficiary will have no liability to the provider or Medicare. *Yale–New Haven Hosp. v. Leavitt,* 470 F.3d 71, 78 n. 5 (2d Cir.2006) (citing 42 U.S.C. § 1395pp(b)). A Medicare beneficiary is considered to have known that services were not covered if written notice has been given to the beneficiary or someone acting on his or her behalf, explaining that "the services were not covered because they did not meet Medicare coverage guidelines." 42 C.F.R. § 411.404(b).

Here, Plaintiff requested prior authorization for a CGM, meaning she requested that SecureHorizons decide whether it would cover a CGM before she obtained it. When her request was denied, Plaintiff had knowledge that the service was not covered under her MA plan or

[3] The Secretary adds that although coverage for a CGM was properly denied, Plaintiff is not left without coverage for diabetic self-monitoring supplies that can help her to control her blood glucose levels. LCD L27231 allows for coverage of testing strips and lancets based on the frequency a person needs to test his or her blood glucose levels, provided the person's treating practitioner documents the need for the increased utilization. A.R. 581.

original Medicare. Indeed, SecureHorizons' denial was upheld through the review by Maximus. Although the ALJ reversed Maximus, Plaintiff knew that SecureHorizons was challenging the ALJ's decision. Given that Plaintiff's request was denied several times already, she knew or should have known that there was a distinct possibility that the ALJ's decision would be reversed. Thus, Plaintiff does not satisfy the requirements to be held harmless for the costs she incurred for the CGM she purchased after knowing that her request for a CGM had been denied several times. A.R. 18-19.

VI. Conclusion

The Secretary's final decision is based on the correct application of the Medicare guidelines covering CGMs. Accordingly, the Secretary respectfully requests that this Court affirm her final decision as it is free from legal error.

Dated this 26th day of November, 2014.

Respectfully submitted,

JAMES L. SANTELLE
United States Attorney

By: /s/ Lisa T. Warwick

LISA T. WARWICK
Assistant United States Attorney
Eastern District of Wisconsin
517 E. Wisconsin Ave.
Milwaukee, WI 53202
State Bar No. 1017754
(414) 297-1700
Facsimile: (414) 297-4394
Lisa.warwick@usdoj.gov

Of Counsel:

William B. Schultz
General Counsel

Alan S. Dorn
Chief Counsel, Region V

Teresa M. Vargas
Assistant Regional Counsel
Department of Health and Human Services
Office of the General Counsel
999 18th Street, Room 400
Denver, Colorado 80202